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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,262

07/09/2007

Wolfgang Hillen

06-40247US

1254

7066

7590

04/28/2010

REED SMITH LLP

2500 ONE LIBERTY PLACE

1650 MARKET STREET

PHILADELPHIA, PA 19103

EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

04/28/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,262	<b>Applicant(s)</b> HILLEN ET AL.	
	<b>Examiner</b> CELINE X. QIAN	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-24 is/are pending in the application.
- 4a) Of the above claim(s) 9-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1106,1207</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> .                 |

### **DETAILED ACTION**

Claims 1, 4-24 are pending in the application.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 2/2/2010 is acknowledged. The traversal is on the ground(s) that the international proceeding of the application found claims 1-22 fulfill unity of invention requirement and has already searched prior art for the pending claims. Applicants further argue that Toby is not prior art because its teaching concerns the yeast two hybrid method, which is used to detect protein-protein interaction, wherein the Tip-tag system presented in this application is used to detect a protein interaction. Applicants further assert that the special technical feature was not taught by Toby since (a) and (b) steps must be considered as a whole.

The above arguments have been fully considered but are not found persuasive for following reasons. 37 CFR 1.499 set forth the following requirement for unity of invention during the national stage: If the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under § § 1.143 and 1.144. see MPEP 1893.03(d) [R-7]. In response to Applicant's argument with regard to international proceeding, Applicants are reminded that this is a factual showing that the unity of invention exists between the inventions claimed in the national stage application. In response to Applicants' argument directed to the difference between the prior art

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invention and the Tip-tag system presented in the instant application, Applicants are reminded that the instant claims scope are not limited to the so called Tip-tag system described in the specification. As stated in the previous office action, the “special technical feature” of Group I is a regulatory biomolecule being a nucleic acid binding molecule or an allosterically controlled ribonucleic acid molecule, and a interaction partner encoded by a nucleic acid molecule encoding a tagged polypeptide, expressed both in a cell. The yeast two hybrid system taught by Toby, although it is used for a different purpose, read on the special technical feature of claim 1, thereby such special technical feature does not make a contribution over the prior art. Assessing the expression of a gene through the expression of a reporter is not an inventive step because such practice is well known in the art thus not considered. PCT Rule 13.2 requires that the special technical feature be considered with respect to both novelty and inventive step. Therefore, for reason set forth in the previous office action and above, the restriction requirement is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 9-24 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1, 4-8 are currently under examination.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 11/17/06 and 12/12/2007 have been considered by the examiner.

#### ***Sequence Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2).

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However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821(d) because the Application contains references to sequences in the specification that fail to recite a "SEQ ID NO." For example, the sequences disclosed on pages 24-27 fail to recite a SEQ ID NO and they are not presented in the sequence listing. The above reasons are set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Toby et al (see IDS).

Toby et al. disclose a method of using the classical and modified two hybrid based approaches to study protein-protein interaction. Toby et al. disclose transforming a yeast cell

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expressing a regulatory molecule, a bait that comprises a DNA binding domain from a transcriptional regulator, *lexA*, with interaction partner of tagged polypeptide fused to activation domain of B42, and detecting the reporter readout of *lacZ* (see page 204, 2<sup>nd</sup> col., 2<sup>nd</sup> full paragraph, and Table 1). Toby et al. further disclose split two hybrid system comprising TetR repressor as the binding polypeptide (see for example, Figure 3 and legend). Therefore, Toby et al. disclose the instantly claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Toby et al., in view of Manfredi et al (US 6,828,112).

The teaching of Toby et al. has been discussed above. However, Toby et al. do not teach using antibiotic resistance gene as the reporter protein.

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Manfredi et al. teach a method of detecting protein-protein interaction base on the generation of a reporter gene that is detectable when the protein fusion leads to trans-splicing (see abstract). Manfredi et al. teach a number of reporters may be employed in said method including antibiotic resistance gene (see col. 22, lines 50-56, and the bridging paragraph of col. 22 and 23).

It would have been obvious to an ordinary skill in the art reading both the teaching of Toby et al. and Manfredi et al. to realize that antibiotic resistance gene can be employed as the reporter protein in the two hybrid system taught by Toby et al. The ordinary skill in the art would recognize that the antibiotic reporter can be used to positively select host cells expressing the desired bait. The level of skill in the art is high. Absent evidence from the contrary, the ordinary artisan would have reasonable expectation of success to construct a reporter protein linked to a promoter which responds to the binding and activation of the regulatory biomolecule in the presence of the interaction partner. Combining prior art known methods to achieve a predictable results is within the capability of an ordinary skill in the art. Therefore, the claimed invention would have been *prima facie* obvious to an ordinary artisan at the time the invention was made.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /  
Primary Examiner, Art Unit 1636